UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560

44183 7590 01/05/2007

BAXTER HEALTHCARE CORPORATION
ONE BAXTER PARKWAY
MAIL STOP DF2-2E
DEERFIELD, IL 60015

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	09/553,969	WALLACE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,19-21 and 23-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,19-21 and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE, amendment and response all dated 10-2-06 is acknowledged.

Claims 1, 19-21 and 23-36 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-2-06 has been entered.

The following rejection of record has been maintained:

1. Claims 1, 20, 21, 23, 25, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,818,517 to Kwee et al (Kwee).

Kwee et al discloses a pharmaceutical preparation comprising a hydrogel polymer and a drug, which is introduced by means of an injection syringe, which reads on the instant applicator having an extrusion orifice. Kwee teaches that the composition provides water necessary for the preparation of the highly viscous hydrogel that is already part of the total composition (col. 1). Thus, the composition of Kwee does not contain any free aqueous phase other than the water that forms a part of the hydrogel. Kwee teaches that the polymer has a swelling capacity but does not state the claimed percentages. However, Kwee teaches dextrin as a suitable polymer (examples), which

is a polysaccharide and thus the swelling capacity is inherent to dextrin of Kwee et al. Further, the claimed property of in vivo degradation time being less than one year is inherent to the polymer because Kwee teaches the same class of polymer i.e., a polysaccharide.

2. Claims 19, 24, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee).

Instant claims are directed to protein and non-biological hydrogel and particle size of the hydrogel. While Kwee does not explicitly teach the claimed features, Kwee teaches a hydrogel polymer and suggests polymers such as dextran, starch, polyvinyl alcohol, etc (col. 2) are capable of swelling in water and homogenously injected out of the syringe without causing any practical problems and release the drug slowly over a period of time. Further, Kwee teaches that the polymer is in the form of dry particles (claims) and also suggests that the hydrogel can be used in combination with any drug such as locally active drugs, bactericidal, anti-inflammatories, etc. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a particulate natural or synthetic (non-biological) polymer such as polyvinyl alcohol, having an appropriate particle size, as a hydrogel in combination with the any desired drug because Kwee suggests that the dry particulate polymer which has a capability to swell is useful in releasing the drug over a long period of time without having the conventional drawbacks such as water being separated from the hydrogel during injection at the site of interest.

3. Claims 26-29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee) in view of Berg et al.

Kwee fails to teach the claimed protein polymer, a clotting agent such as thrombin, or the claimed combination of polymers.

Berg teaches a collagen wound dressing material comprising resorbable collagen particles of 50 to 350 microns. Berg also teaches addition of several wound-healing agents such as growth factors, enzyme inhibitors, angiogenesis factors etc (col. 4). Berg teaches that collagen would dressings are capable of swelling at the desired ratios and still be injectable (examples 5 and 10). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ particulate collagen of Berg as a hydrogel in the teachings of Kwee and use the hydrogel alone or in combination with the hydrogels of Kwee for releasing drugs such as wound healing agents because Berg suggests that collagen dressings are capable of being resorbable, allow cellular in growth, and protect the wound to be treated while still permitting the required diffusion of gases and liquids.

Response to Arguments

Applicant's arguments filed 10-2-06 have been fully considered but they are not persuasive.

Sierra- Claims 1, 19-24, 28, 29 and 34:

Applicants' arguments are moot because the rejection of claims over Sierra has been withdrawn.

Kwee- claims 1, 20, 21, 23, 25, 30 and 35:

Applicants arguments regarding the teachings of Kwee and the response to the arguments from the previous action dated 5-2-06 is incorporated here. It is argued that according to claim 1 of Kwee requires two phases. The argument is not persuasive because claim 1 of Kwee nowhere states 2 separate phases and instead only teaches that a polymer capable of swelling. In fact, claim 2 clarifies this because a second compartment of the container contains water that swells the polymer. In this regard, the absorbing agent of Kwee is present only to absorb excess water separated out of hydrogel. For the same reasons, applicants' argument regarding the teaching of Kwee at col. 1, L 35-40 is not persuasive. Further, the teaching in col. 3, L 16-28 only substantiates the office position that the hydrogel formed does not have excess water due to the presence of a thickening agent. Kwee teaches that the two-compartment syringe contains swellable polymer in one compartment and a thickening agent in either or both the compartments (lines bridging col. 1-2). Kwee teaches that the thickening (water-soluble) agent is added to absorb additional water that is left after the insoluble polymer is swelled. Thus, the insoluble polymer forms a hydrogel alone, without a need for the water-soluble thickener and hence the aqueous colloid is made of the swollen polymer alone. The water-soluble thickener is present only to absorb the remaining water and is very evident from the teachings of Kwee that the latter is not a part of the swollen polymer and instead is present in the water in such low amounts that after the polymer swells the thickener absorbs the remaining water.

Further, applicants defines the term "hydrogel" (page 18, lines 7-11) as a composition "comprising" a single aqueous phase colloid and also describes the hydrogel as "comprises", thus allowing for the additional components such as thickening agents of Kwee to be present. Applicants' argument regarding the claimed subunit size and degradation rate of claims 1 and 35 are not persuasive because the above claims only need one of the three features and the hydrogels do not have excess water so as to swell above their capacity. Instant specification describes that a fully hydrated gel possesses the claimed equilibrium swell (page 8, L 18-21). According to Kwee, the polymer swells and the thickener absorbs excess water. Thus, it is implicit form the Kwee that only after the polymer is fully hydrated that there will be any excess water left for the thickener to absorb. Accordingly, the teachings of Kwee meet the argued requirement of a proper inherency test. Therefore, the rejection has been maintained.

Kwee: claims 19, 24, 31, 32 and 36:

Applicants argue that Kwee fails to teach or suggest all the limitations of claim 1 and for the same reasons; Kwee fails to teach the elements of instant claim 36. It is argued that claims 24, 31 and 32 are directly dependent from claim 1 and hence should be allowable for the above reasons. Applicants' arguments are not persuasive because as explained in the previous paragraph, Kwee discloses the claimed product. Further, with respect to the non-biological polymer of claim 36, Kwee suggests polyvinyl alcohol, dextrin and starch as equivalents for their suitability as a swelling polymer. Kwee also suggests adding drugs to composition comprising hydrogel for delivering to the site of application. Therefore it would have been obvious for one of an ordinary skill in the art

at the time of the instant invention to use a particulate natural or synthetic (non-biological) polymer such as polyvinyl alcohol, having an appropriate particle size, as a hydrogel in combination with the any desired drug because Kwee suggests that the dry particulate polymer which has a capability to swell is useful in releasing the drug over a long period of time without having the conventional drawbacks such as water being separated from the hydrogel during injection at the site of interest.

Kwee in view of Berg:

Applicants argue that Kwee fails to teach or suggest each and every element of independent claims and that Berg fails to remedy the deficiencies of Kwee because Berg fails to disclose a single-phase aqueous colloid that is substantially free from a free aqueous phase. It is argued that Berg fails to teach the limitations of claim 1, claim 34 and also lacks suggestion for claims 26-29 and 33. Applicants' arguments have been considered but not found persuasive because as explained in the previous action and previous paragraphs, Kwee does teach the claimed product. The motivation to add the collagen hydrogels of Berg to the composition of Kwee comes from the fact that both Kwee and Berg are directed to hydrogel polymers for therapeutic purposes and Berg suggests that collagen hydrogels are capable of swelling, injectable and are resorbable by the body. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ particulate collagen of Berg as a hydrogel in the teachings of Kwee and use the hydrogel alone or in combination with the hydrogels of Kwee for releasing drugs such as wound healing agents because Berg suggests that

collagen dressings are capable of being resorbable, allow cellular in growth, and protect the wound to be treated while still permitting the required diffusion of gases and liquids.

The following is a new rejection:

Claim Rejections - 35 USC § 102

Claims 1, 19-21, 24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,424,208 to Wallace et al (Wallace).

Wallace discloses an injectable collagen implant material and a method of augmenting soft tissue comprising particles of crosslinked collagen and reconstituted fibrous collagen. Wallace particularly teaches the preparation of cross-linked gel particles, wherein a collagen gel is formed, followed by cross-linking. The cross-linked gel is then comminuted, fragmented or shredded by extruding through syringes (col. 4, L 40-68 and col. 5, L 1-9). Thus, the final hydrogel comprises a crosslinked gel and fibrous gel, which meets the claim limitation "substantially free of free aqueous phase". The process of preparing the hydrogel described by Wallace includes the same process steps that are also described in the instant specification (page 34, example 9) and hence meets the limitation "single phase aqueous colloid". Further, because of the process being same, the claimed characteristics i.e., sub unit size, swell and degradation time are also inherent to the gels of Wallace.

4. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,424,208 to Wallace et al (Wallace), as applied to claims 1, 19-21, 24 and 28 above, and further in view of US 6,110,484 to Sierra.

Claim 34 is directed to a gelatin hydrogel composition. Wallace only teaches collagen hydrogels.

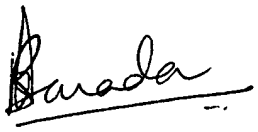
Sierra discloses a biomedical implant comprising a matrix material and a biodegradable porosifying agent, for a mechanically stable implant that allows for tissue and fluid influx into the matrix.

Sierra teaches collagen, gelatin, polyvinyl alcohol, polycarbonates etc., as suitable in the composition as biodegradable and biocompatible matrix and porosifying agents (col. 4). Sierra teaches that the above biodegradable matrix materials are suitable because they degrade a slower rate and also suitable for delivering therapeutic agents. Sierra further exemplifies hydrogels containing gelatin. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ gelatin or collagen as suitable hydrogels for tissue implantation or wound healing because Sierra suggests both collagen and gelating gels as equivalent in wound healing or tissue remodeling. A skilled artisan would have expected to achieve the same dressing or remodeling tissue with either collagen or gelatin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Art Unit 1615
December 26, 2006

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER